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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,311	01/22/2002	Jan-Michael Peters	0652.2290001	4782

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/051,311	<b>Applicant(s)</b> PETERS ET AL.	
	<b>Examiner</b> Christian L. Fronda	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-15 is/are rejected.
- 7) ☒ Claim(s) 6 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 06/14/2005 has been entered.
2. Claims 1-6 and 11-16 are pending and under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. Claims 1-5 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a test compound that inhibits the proteolytic activity of a separase using a substrate peptide consisting of SEQ ID NO:9, SEQ ID NO: 11, or SEQ ID NO: 12; does not reasonably provide enablement for any method for identifying a test compound that inhibits the proteolytic activity of a separase using any substrate peptide comprising an amino acid sequence EXXR, wherein X is any amino acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments filed 6/14/2005 have been acknowledged but are not persuasive. The examiner respectfully disagrees with applicants' position that making and using separase substrates comprising an amino acid sequence EXXR would require undue experimentation for reasons of record as supplemented below.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for identifying a test compound that inhibits the proteolytic activity of a separase using any substrate peptide comprising an amino acid sequence EXXR, wherein X is any amino acid. The specification

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provides guidance and working examples for the recited method using peptide substrates of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12.

The specification nor the general knowledge of those skilled in the art do not provide guidance, prediction, and working examples showing that any of the 400 possible EXXR sequences shown on Exhibit 1 other than SEQ ID NOs: 9, 11, and 12 can be used as peptide substrates successfully in the claimed method. Thus, an undue amount of trial and error experimentation must be performed to search and screen for any peptide substrate including the 400 possible EXXR sequences shown on Exhibit 1 comprising the amino acid sequence EXXR which can be used in the method

While applicants have presented 400 possible EXXR sequences shown on Exhibit 1, there is no presentation of non-naturally occurring amino acids (e.g., D-alloisoleucine) as well as different types of amino acid residue modifications including acylation as encompassed by the claims. Thus, the presented 400 possible EXXR sequences is not a complete list of all possible EXXR sequences that must be searched and screened for as a suitable separate peptide substrate.

Teachings from the specification regarding screening and searching for the separate peptide substrates comprising the amino acid sequence EXXR is not guidance for making the claimed invention. Furthermore, searching and screening for the claimed invention is outside the realm of routine experimentation.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

4. Claims 1-5 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Applicants' arguments filed 6/14/2005 have been acknowledged but are not persuasive. The examiner respectfully disagrees with applicants' position that the genus of separate substrates as encompassed by the claims is adequately described and that the disclosed species are representative of the genus of EXXR peptide substrates. Applicants argue that the claims include structural limitations which limits the variability among species and that the specification provides assay for identifying members of the genus that have the recited structural element as illustrated in the USPTO Written Description Guidelines Example 14.

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The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The claims are genus claims that encompass a genus of peptides of any amino acid sequence, structure, and biological function comprising the amino acid sequence EXXR, where X is any amino acid, or comprising the amino acid sequence of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12. The scope of the genus includes many peptides with widely differing amino acid sequences as well as widely differing structural, chemical, and biophysical properties. The scope of the genus is not limited to peptides "consisting" of EXXR, SEQ ID NO: 9, 11, or 12 since the claims specifically recite the phrase "comprising an amino acid sequence".

The disclosed peptides of consisting of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12 are not representative of the claimed genus since other genus members include peptides and proteins with widely differing amino acid sequences, structures, and biological functions. The specification does not provide a description of an amino acid sequence and structure common to the members of the claimed genus of peptides comprising the amino acid sequence EXXR, where X is any amino acid, or comprising the amino acid sequence of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12. Thus, the skilled artisan cannot predict the structure of other species encompassed by the claimed genus.

Example 14 of the USPTO Written Description Guidelines is directed toward a full-length protein having the specific amino acid sequence of SEQ ID NO: 3 which catalyzes a chemical reaction. However, the instant invention encompasses peptide substrates that do not catalyze any chemical reaction, which is not analogous to Example 14. Furthermore, in contrast to Example 14 the claimed invention discloses only a minimal amount of sequence information for the genus of separase peptide substrates. Thus, applicants' argument that the claimed invention meets the written description requirement in view of Example 14 of the Patent Office's Written Description Guidelines is not accurate.


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In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed genus of peptides of any amino acid sequence, structure, and biological function comprising the amino acid sequence EXXR, where X is any amino acid, or comprising the amino acid sequence of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12.

***Conclusion***

5. No claim is allowed.
6. Claims 6 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.
8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
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